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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,135	02/13/2002	Akemichi Baba	010541A	5435
38834	7590	02/28/2005	EXAMINER	
WESTERMAN, HATTORI, DANIELS & ADRIAN, LLP 1250 CONNECTICUT AVENUE, NW SUITE 700 WASHINGTON, DC 20036			QIAN, CELINE X	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 02/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b><i>Advisory Action Before the Filing of an Appeal Brief</i></b>	<b>Application No.</b> 10/073,135	<b>Applicant(s)</b> BABA ET AL.	
	<b>Examiner</b> Celine X Qian Ph.D.	<b>Art Unit</b> 1636	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 08 February 2005 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE.

1. ☒ The reply was filed after a final rejection, but prior to filing a Notice of Appeal. To avoid abandonment of this application, applicant must timely file one of the following replies: (1) an amendment, affidavit, or other evidence, which places the application in condition for allowance; (2) a Notice of Appeal (with appeal fee) in compliance with 37 CFR 41.31; or (3) a Request for Continued Examination (RCE) in compliance with 37 CFR 1.114. The reply must be filed within one of the following time periods:

- a) ☒ The period for reply expires 5 months from the mailing date of the final rejection.  
 b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection.  
 Examiner Note: If box 1 is checked, check either box (a) or (b). ONLY CHECK BOX (b) WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### NOTICE OF APPEAL

2. ☐ The reply was filed after the date of filing a Notice of Appeal, but prior to the date of filing an appeal brief. The Notice of Appeal was filed on \_\_\_\_\_. A brief in compliance with 37 CFR 41.37 must be filed within two months of the date of filing the Notice of Appeal (37 CFR 41.37(a)), or any extension thereof (37 CFR 41.37(e)), to avoid dismissal of the appeal. Since a Notice of Appeal has been filed, any reply must be filed within the time period set forth in 37 CFR 41.37(a).

#### AMENDMENTS

3. ☒ The proposed amendment(s) filed after a final rejection, but prior to the date of filing a brief, will not be entered because  
 (a) ☐ They raise new issues that would require further consideration and/or search (see NOTE below);  
 (b) ☐ They raise the issue of new matter (see NOTE below);  
 (c) ☒ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or  
 (d) ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet. (See 37 CFR 1.116 and 41.33(a)).

4. ☐ The amendments are not in compliance with 37 CFR 1.121. See attached Notice of Non-Compliant Amendment (PTOL-324).  
 5. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.  
 6. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).  
 7. ☒ For purposes of appeal, the proposed amendment(s): a) ☒ will not be entered, or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.  
 The status of the claim(s) is (or will be) as follows:  
 Claim(s) allowed: \_\_\_\_\_.  
 Claim(s) objected to: \_\_\_\_\_.  
 Claim(s) rejected: 1-18.  
 Claim(s) withdrawn from consideration: \_\_\_\_\_.

#### AFFIDAVIT OR OTHER EVIDENCE

8. ☐ The affidavit or other evidence filed after a final action, but before or on the date of filing a Notice of Appeal will not be entered because applicant failed to provide a showing of good and sufficient reasons why the affidavit or other evidence is necessary and was not earlier presented. See 37 CFR 1.116(e).  
 9. ☐ The affidavit or other evidence filed after the date of filing a Notice of Appeal, but prior to the date of filing a brief, will not be entered because the affidavit or other evidence failed to overcome all rejections under appeal and/or appellant fails to provide a showing a good and sufficient reasons why it is necessary and was not earlier presented. See 37 CFR 41.33(d)(1).  
 10. ☐ The affidavit or other evidence is entered. An explanation of the status of the claims after entry is below or attached.

#### REQUEST FOR RECONSIDERATION/OTHER

11. ☒ The request for reconsideration has been considered but does NOT place the application in condition for allowance because:  
The proposed amendment will not overcome the enablement rejection of the record because the specification does not teach how to use the claimed mouse with the alleged psychomotor behavior. As discussed in the previous office actions, the claimed mouse is not a valid model for any human psychiatric disorder. The specification only discloses a homozygous PACAP knockout mouse having the phenotype of hyperactivity which is reversible by haloperidol, increased exploratory activity and reduced anxiety. It is unclear whether human with the same disclosed phenotype is result from the disruption of the PACAP gene. In addition, contrary to Applicants' assertion, neither the specification nor prior art teach an association between a psychiatric disorder and PACAP disruption in human, and the overall phenotype of the mouse does not represent any psychiatric disorder in human. Therefore, the specification fails to teach how to use the claimed mouse as a psychiatric model. With regard to Teledy and Hashimoto's teaching, the previous office action already indicate that it only teaches PACAP disruption may be associated with LTP in a mouse, and such teaching does not predict the same relationship in the human. Likewise, the Hashimoto reference (PNAS) submitted on 2/8/05 does not teach how to use the claimed mouse as a psychiatric model as disclosed in the specification. As such, it cannot be relied on to provide support for the enablement of the claimed invention. Therefore, for reasons discussed in the previous office action and above, the claimed invention is not enabled.  
 12. ☐ Note the attached Information Disclosure Statement(s). (PTO/SB/08 or PTO-1449) Paper No(s). \_\_\_\_\_  
 13. ☐ Other: \_\_\_\_\_.

U.S. Patent and Trademark Office  
PTOL-303 (Rev. 9-04)

**Advisory Action Before the Filing of an Appeal Brief**

Part of Paper No. 0205

Continuation of 3. NOTE: The proposed amendment are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal. Amendment of the claims that drawn to a transgenic mouse having psychomotor behavior does not overcome the problems of enablement raised in the office action mailed on 9/8/04 (also see explanation below). Therefore, the proposed amendment will not be entered.

**CELIAN QIAN**  
**PATENT EXAMINER**

